IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INT'L GMBH, and BIOGEN MA INC.	:	
Plaintiffs,	:	
v.	:	C.A. No. 17-823-LPS (Consolidated)
AMNEAL PHARMACEUTICALS LLC, ET AL.	:	
Defendants.	:	

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MEMORANDUM OPINION

March 7, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, "Biogen" or "Plaintiffs") filed suit against multiple defendants in this now-consolidated action under the Hatch-Waxman Act as a result of Defendants' efforts to market a generic version of Biogen's Tecfidera (dimethyl fumarate) product. Biogen filed complaints alleging infringement of U.S. Patent Nos. 6,509,376 ("the '376 patent"), 7,320,999 ("the '999 patent"), 7,619,001 ("the '001 patent"), 7,803,840 ("the '840 patent"), 8,759,393 ("the '393 patent"), and 8,399,514 ("the '514 patent") (collectively, "patents-in-suit" or "asserted patents").

Presently before the Court is the issue of claim construction. While most of the Defendants agree with Plaintiffs that no claim construction is necessary, at least three Defendants – Hetero, Zydus, and Pharmathen – seek construction of the term "microtablets or micropellets" as used in the '001 Patent. The parties completed briefing on November 30, 2018. (D.I. 194, 195, 202, 203) The Court held a claim construction hearing on January 9, 2019. (*See* D.I. 222) ("Tr.")

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citation and internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent "specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . . [b]ecause claim terms are normally used consistently throughout the patent." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven

when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (alteration in original) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

"In some cases, . . . the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in

the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERM[1]

"microtablets"[2]

Plaintiffs Plain and ordinary meaning: small tablets, such that multiple microtablets can be included in a single pharmaceutical preparation
Hetero/Zydu tablets or pellets having a mean diameter of 2mm or less

[1]The Court will also adopt the parties' agreed-upon constructions.

[2]This term appears in claims 15, 16, and 19-21 of the '001 Patent.

Pharmathen tablets or pellets having a mean diameter of 5mm or less Indefinite
Court tablets or pellets having a fraction of a single pharmaceutical dose and having a size such that they may pass through a human pylorus to the duodenum

The parties agree that microtablets are generally smaller than conventional tablets, but dispute whether, in the context of this patent, they are defined by a specific size. (D.I. 194 at 8; D.I. 195 at 9) Plaintiffs propose a construction that lacks a definite size requirement ("small tablets"), provided, however, that the microtablets are small enough that it would require more than one microtablet of active pharmaceutical ingredient for a "single pharmaceutical preparation." Defendants propose different sized-based requirements – mean diameters of no more than 2.0 mm or 5.0 mm – but their specific proposed size requirements lack support in the specification and claims. *See*, *e.g.*, '001 Patent, cls. 20, 21 (leaving open possibility that microtablets may be larger than 2.0 mm when accounting for their coating); D.I. 194 at 14-16 (relying on extrinsic evidence for 5.0 mm mean diameter limit).

The parties agreed at oral argument that each microtablet must contain a fraction (i.e., a part less than the whole) of a single pharmaceutical dose,[3] such that a single dose requires a plurality of microtablets. (Tr. at 26, 31; *see also* '001 Patent, col. 5 ll. 41-63 (noting that microtablets contain "smaller dosage" than traditional tablets); col. 6 l. 65-col. 7 l. 43 (providing three examples where plurality of microtablets or pellets are filled into single capsule))[4] The parties also agreed that each microtablet must be sized such that it can pass from a human

[3]The Court understands "a single pharmaceutical dose" to mean the amount of active ingredient necessary to achieve the intended efficacy in humans.

[4] The parties also agreed that not every microtablet in a particular formulation is required to have the same fraction of active ingredient. (*See* Tr. at 10, 17)

stomach, through the pylorus, to the duodenum. (Tr. at 23-26) These requirements find support in the specification and – unlike reading into the claims Defendants' proposed size restrictions – do not create concerns under the doctrine of claim differentiation. *See* '001 Patent, col. 5 ll. 41-54 ("The micro-tablets are incrementally released by the stomach and passed into the small intestine. . . ."); *see also* D.I. 195 at 8-9 (discussing how doctrine of claim differentiation may be violated by reading in specific size requirements). The Court's construction is based on these conclusions.

III. CONCLUSION

The Court will construe the disputed term as explained above. An appropriate Order follows.